

### **REMARKS**

Applicant respectfully requests reconsideration. Claims 19-39 were previously pending in this application. Claim 19 is amended herein. No claims are canceled. Claims 19-39 are still pending for examination with claim 19 being an independent claim. No new matter has been added.

#### **Priority Claim**

Applicant has amended the related applications paragraph on the first page of the specification to reflect that the earliest effective priority date of the claims currently pending is October 30, 1996. The claim of priority to US Patent Number 6,194,388 and US patent application number 08/276,358 has been dropped. The change is consistent with the priority claim agreed to in Interference 105,526 with respect to related claims in US 09/337,584. An application data sheet reflecting this change has also been filed concurrently. No new matter has been added.

#### **Rejection Under 35 U.S.C. 112**

Claims 19-39 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 19 to clarify that the immunostimulatory oligonucleotide is administered in an effective amount to treat asthma.

#### **Double Patenting**

Claims 19-39 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 42-47, 49-53, 56, 57, 82-85, 90, 92, 94, 96, 98, 100, 102 and 103 of copending Application No. 09/337,584.

The rejection is a provisional one because no allowable claims have been identified. Although US 09/337,584 has been returned from the Board, a notice of allowance has not yet been issued. If allowable subject matter is identified Applicant will address the merits of the rejection over the allowable subject matter.

Claims 19-39 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 23, 31, 32 and 34-37 of copending Application No. 10/769,282.

The rejection is a provisional one because no allowable claims have been identified. If allowable subject matter is identified Applicant will address the merits of the rejection over the allowable subject matter.

Claims 19-39 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-29 and 31-33 of copending Application No. 10/894,862.

The rejection is a provisional one because no allowable claims have been identified. If allowable subject matter is identified Applicant will address the merits of the rejection over the allowable subject matter.

Claims 19-39 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 11-38, 40 and 42-49 of U.S. Patent No. 7,605,138. Specifically, the Office asserts that although US 7605138 does not recite the treatment of asthma, "this would be the result since the methods steps are the same." (Office Action page 4).

Claims 19-39 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9-26, 48 and 49 of U.S. Patent No. 7,576,066. Specifically, the Office asserts that although US 7,576,066 does not recite the treatment of asthma, "this would be the result since the methods steps are the same." (Office Action page 5).

Claims 19-39 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9-23, 43, 44 and 46-48 of U.S. Patent No. 7,569,553. Specifically, the Office asserts that although US 7,569,553 does not recite the treatment of asthma, "this would be the result since the methods steps are the same." (Office Action page 5).

Although Applicant disagrees with each of the rejections, claim 19 has been amended to add the limitation that the oligonucleotide is administered to a subject having asthma. Since the pending

claims require that the oligonucleotide be administered to a subject having asthma, the method steps are not the same as the method steps claimed in US 7,605,138; 7,569,553; and 7,576,066.

The instant claims are not properly rejected under the doctrine of obviousness type double patenting over US 7,605,138; 7,569,553; and 7,576,066 because US 7,605,138; 7,569,553; and 7,576,066 and the instant patent application are not commonly owned and do not have identical inventive entities. The cited patents do not have common ownership with the instant patent application, as common ownership is defined in MPEP 706.02(I). MPEP 706.02(I) states that the "term 'common ownership' means wholly owned by the same person(s) or organization(s) at the time the invention was made." The instant patent application is owned by the University of Iowa Research Foundation and the inventors are Krieg and Kline. US 7,605,138; 7,569,553; and 7,576,066 are owned by Coley Pharmaceutical Group (now owned by Pfizer) and the inventor is Krieg. The University of Iowa Research Foundation is not an owner of US 7,605,138; 7,569,553; and 7,576,066 and Coley Pharmaceutical Group is not an owner of the instant patent application.

An obviousness type double patenting rejection is inappropriate in this situation. Obviousness type double patenting relates to common ownership. As stated in MPEP 804IIB1 "Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a *commonly owned patent*, or a non-commonly owned patent but subject to a joint research agreement." (emphasis added). An obviousness-type double patenting rejection requires the subject application and cited patent to be commonly owned, rather than to be commonly assigned. According to MPEP 706.02(I) the "term 'common ownership' means wholly owned by the same person(s) or organization(s) at the time the invention was made." Although the patent application and the patent have one common inventor and no owners in common, the application and patent are not commonly owned (common ownership requires all of the same owners). An obviousness-type double patenting rejection requires the subject application and cited patent to be commonly owned.<sup>1</sup> Thus, it is requested that the rejection be withdrawn.

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<sup>1</sup> See MPEP §804; *Longi*, 759 F.2d at 895, 225 USPQ at 650.

Even if double patenting were an appropriate rejection in the instant case, the rejection should not stand based on a two-way test of obviousness. It appears that the Office applied a one-way determination of obviousness, as outlined in MPEP 804 II B (1)(a) in trying to resolve the issue of double patenting. Applicant believes that in the instant case a two-way determination of obviousness would be the proper test instead.

As noted in MPEP 804 II B(1)(b), a two-way test is to be applied if the patent is the later filed application and "only when the applicant could not have filed the claims in a single application and there is administrative delay"

First, in order for the two-way obviousness determination to be proper, the patent must have been filed later than the pending application. The instant patent application has an earlier priority date than each of US Patent numbers 7,605,138; 7,569,553; and 7,576,066. Thus, the instant patent application was filed prior to the issued patents.

Second, the two-way test is proper only when Applicant could not have filed the claims in a single application. The instant pending patent application and US Patent 7,605,138; 7,569,553; and 7,576,066 are not commonly owned and do not have identical inventorship. The instant patent application could not have been filed in a single application with the issued patents because the application containing the invention of the instant patent application was already pending at the time the issued patents were invented and filed as patent applications. The inventions were separate and distinct and did not take place at the same time. Thus, this criterion for the two-way test to be proper is met.

Third, the two-way test is proper only if there was administrative delay with respect to the prosecution of the pending patent application. In the instant case, Applicant pursued the claims directed to use of the immunostimulatory oligonucleotides in the treatment of asthma in a reasonable manner and did not cause the delay in issuance of the claims. The delay was administrative. Applicant filed the instant claims on December 22, 2003 claiming priority to earlier filed applications. Applicant continuously prosecuted the patent application for the instant invention without filing continuations or otherwise interrupting prosecution. Applicant respectfully submits that the PTO controlled the rate of prosecution leading to the issuance of the cited patents.

Application of the two way test would compel a conclusion of non-obviousness under the doctrine of obviousness type double patenting. According to the MPEP 804 II B(1)(b), “[w]hen making a two-way obviousness determination where appropriate, it is necessary to apply the Graham obviousness analysis twice, once with the application claims as the claims in issue, and once with the patent claims as the claims in issue. Where a two-way obviousness determination is required, an obvious-type double patenting rejection is appropriate only where each analysis compels a conclusion that the invention defined in the claims in issue is an obvious variation of the invention defined in a claim in the other application/patent. If either analysis does not compel a conclusion of obviousness, no double patenting rejection of the obvious-type is made, but this does not necessarily preclude a nonstatutory double patenting rejection based on the fundamental reason to prevent unjustified timewise extension of the right to exclude granted by a patent. In re Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968)”.

In the instant situation, the pending application is available as a reference for rejection under 35 USC 102(e) against US Patents 7,605,138; 7,569,553; and 7,576,066 because it has a priority date more than a year earlier than these patents. The Patent Office issued the claims of U.S. Patent 7,605,138; 7,569,553; and 7,576,066 and, thus, considered the claims in U.S. Patent 7,605,138; 7,569,553; and 7,576,066 to be novel and non-obvious over the disclosure of the instant patent application. Therefore, at least one arm of the two-way test compels a conclusion of non-obviousness. It is clear that application of the two-way test, which would be proper in this case, would result in a finding of non-obviousness of the pending claims.

Withdrawal of the nonstatutory obviousness-type double patenting rejection is respectfully requested.

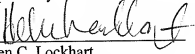
**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C1039.70073US00.

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Respectfully submitted,

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